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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,462

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

07/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/784,462	<b>Applicant(s)</b> BERRA ET AL.	
	<b>Examiner</b> Brian E. Pellegrino	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-21, 24-29, 40-60, 65-67, 70-72, 75-77, 80-82, 85-87, 90-92 and 95-97 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/12/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7-9, 22, 23, 30-39, 61-64, 68, 69, 73, 74, 78, 79, 83, 84, 88, 89, 93, 94 and 98-109.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/27/09 has been entered.

### ***Claim Objections***

Claims 40,41 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. If the centerline and longitudinal axis are parallel then that would mean the longitudinal support member is reverse mirror symmetrical to both. Claims 40,41 recite the longitudinal support member is “substantially” reverse mirror symmetrical with respect to the centerline and thus broadens the claim scope. This is improper.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18,53,80-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson et al. (WO 98/23242). Fig. **21** shows a tubular graft body having a proximal end and a distal end including a structural framework having at least two stents **38,40** each respectively connected (page 19, lines 2,3) to the tubular graft body adjacent the proximal distal ends to define a separation distance there between with a longitudinal support member **50'** shorter than the separation distance. The support member is connected to the graft body between (Fig. 19) the at least two stents to form a gimbal at at least one of said proximal and distal ends of said graft body. Regarding claim 53, the graft is fully capable of expanding to have a diameter of the vessel in which it is implanted, page 20, lines 3-6. Since the stent graft is designed to span a length of a vessel, it has a linear profile. It can also be seen it has a circular cross-section.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,6,10,14,15,19,40,41,43,47,49,51,65-67,70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 98/23242) in view of Hess et al. (5545210). Fig. 19 shows a tubular graft body **22'** having a longitudinal axis and a circumference with a structural framework having at least two Z-stents **38,40** connected circumferentially (Fig. 21) to the graft body and a longitudinal support member **50'** connected to the graft body. Robinson discloses the longitudinal support members are metal, page 14. However, Robinson et al. do not explicitly state the longitudinal supports are curved such that a centerline is parallel to the longitudinal axis and when viewed in such orientation the

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longitudinal axis and said centerline are aligned with one another, thus the support member being reverse-mirror symmetrical with respect to the longitudinal axis. Hess et al. teach (Fig.3) that stents are connected with a curved (or S-shape) longitudinal support member 7 such that it is aligned with the longitudinal axis and is reverse mirror symmetrical with respect to its length, col. 4, lines 59-62. It would have been obvious to one of ordinary skill in the art to use a curved longitudinal support member as taught by Hess et al. with the stent graft of Robinson et al. such that it provides the ability to travel tortuous vessels and expansion to different diameters if necessary in the vessel, (Hess col. 5, lines 1-4). With respect to claim 2, Robinson discloses (page 14) the longitudinal members are metal, but fails to disclose the metal being nitinol. Hess teaches the stent structures are made from nitinol, col. 4, lines 20,21. It would have been obvious to one of ordinary skill in the art to use nitinol as taught by Hess et al. for the longitudinal support member of Robinson since such a modification only involves routine skill in the art and the material has advantageous properties, Hess, col. 4, lines 25-30. Regarding claim 6, Robinson discloses the longitudinal support members can be connected to the graft via sutures and thus is not a permanent affixation to the structural framework and therefore can be interpreted as independent from the framework, page 14, line 12.

Claims 5,11,12,13,16,17,42,75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 98/23242) in view of Hess et al. '210 as applied to claim 1 above, and further in view of Bolea et al. (6821291). Robinson as modified with Hess is explained supra. However, Robinson in view of Hess fail to disclose the longitudinal member has looped or rounded ends at the extremities. Bolea et al. teach (Fig. 22) a stent with a wire member having looped extremities **184**. Bolea et al. also teach that the loops enable an end to be

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collapsed to remove the stent device, col. 10, lines 31-36. It would have been obvious to one of ordinary skill in the art to use looped ends on a longitudinal wire support member as taught by Bolea et al. and incorporate into the stent graft of Robinson et al. as modified by Hess et al. to provide the ability to remove the prosthesis if necessary.

Claims 48,50,52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 98/23242) in view of Hess et al. '210 as applied to claims 1,15,16 above, and further in view of Hartley et al. (6524335). Robinson in view of Hess is explained supra. However, Robinson as modified with Hess fail to disclose a distal most stent with one more apex more than another of stents. Hartley et al. teach (Fig. 2) a stent graft with a distal stent **1** having an apex more than another of the stents. It would have been obvious to one of ordinary skill in the art to use stents with at least one more apex than other stents to better anchor in the vessel as taught by Hartley et al. and incorporate into the stent graft of Robinson et al. as modified with Hess et al. to improve the seal of the graft against the vessel wall.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 98/23242) in view of Hartley et al. (6524335). Robinson et al. is explained supra. However, Robinson et al. fail to disclose a distal most stent with one more apex more than another of stents. Hartley et al. teach (Fig. 2) a stent graft with a distal stent **1** having an apex more than another of the stents. It would have been obvious to one of ordinary skill in the art to use stents with at least one more apex than other stents to better anchor in the vessel as taught by Hartley et al. and incorporate into the stent graft of Robinson et al. to improve the seal of the graft against the vessel wall.

Claims 20,21,28,55,59,85-87,95-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 98/23242) in view of White et al. (6099558). Robinson et al. is explained above and discloses the invention as claimed. However, Robinson fails to disclose pairs of stents or a third stent. White et al. teach a stent graft (Fig. 3) with a plurality of stents **17** and a tubular graft body **16**. It can also be seen (Fig. 2) that the stent graft has a distal and proximal stents **17a** that extend beyond the graft material and thus are outer stents. It would have been obvious to one of ordinary skill in the art to incorporate additional stents as taught by White et al. such that there are outer stents in the stent graft of Robinson et al. in order to provide more radial support to the vessel wall. Regarding claims 55,59 the graft is fully capable of expanding to have a diameter of the vessel in which it is implanted, page 20, lines 3-6. Regarding claims 85,86,95,96 since the stent graft is designed to span a length of a vessel, it has a linear profile. With respect to claim 87,97 it can also be seen it has a circular cross-section.

Claims 24,29,44,46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 98/23242) in view of White et al. '558 as applied to claim 20 above, and further in view of Hess et al. '210. Robinson in view of White is explained above. However, Robinson as modified with White fail to disclose a curved longitudinal support member. Hess et al. is also explained as before. It would have been obvious to one of ordinary skill in the art to utilize a curved support member as taught by Hess et al. with the stent graft of Robinson as modified with White such that it has more flexibility.

Claims 56,60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 98/23242) in view of White et al. '558 as applied to claim 20,28 above, and further in view of Hartley et al. (6524335). Robinson in view of White is explained supra. However,



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Robinson as modified with White fail to disclose a distal most stent with one more apex more than another of stents. Hartley et al. teach (Fig. 2) a stent graft with a distal stent 1 having an apex more than another of the stents. It would have been obvious to one of ordinary skill in the art to use stents with at least one more apex than other stents to better anchor in the vessel as taught by Hartley et al. and incorporate into the stent graft of Robinson et al. as modified with White et al. to improve the seal of the graft against the vessel wall.

Claims 25-27,45,57,90-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 98/23242) in view of Hess et al. '210 and White et al. '558. Robinson et al. is explained as before. However, Robinson fails to disclose the longitudinal support member is curved or that there are pairs of stents at the ends. Hess et al. teach that curved longitudinal support members are advantageously used in tortuous vessels between pairs of stents explained supra. White et al. teaches (Fig. 3) that plurality of stents are used with a graft for radial support. It would have been obvious to one of ordinary skill in the art to form the longitudinal support being curved as taught by Hess et al. with the stent graft of Robinson et al. and incorporate outer stents as taught by White et al. such that more support is provided to the vessel wall while enhancing flexibility. Regarding claim 26, since the support member is not permanently affixed to the stents, it can be interpreted that it does not touch the inner stents. With respect to claim 27, since the support is connected via sutures, it can be interpreted via movement or implantation in a tortuous vessel, the support is capable of moving to touch a stent. Regarding claim 57, the graft is fully capable of expanding to have a diameter of the vessel in which it is implanted, page 20, lines 3-6. Regarding claims 90,91, since the stent graft is designed to span a length of a vessel, it has a linear profile. With respect to claim 92, it can also be seen it has a circular cross-section.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al. (WO 98/23242) in view of Hess et al. '210 and White et al. '558 as applied to claim 25 above, and further in view of Hartley et al. '335. Robinson in view of Hess and White is explained supra. However, Robinson as modified with Hess and White fail to disclose a distal most stent with one more apex more than another of stents. Hartley et al. teach (Fig. 2) a stent graft with a distal stent 1 having an apex more than another of the stents. It would have been obvious to one of ordinary skill in the art to use stents with at least one more apex than other stents to better anchor in the vessel as taught by Hartley et al. and incorporate into the stent graft of Robinson et al. as modified with Hess et al. and White et al. to improve the seal of the graft against the vessel wall.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1,15,16,18,20,25,28 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700  
/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738